DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL – 10345-02
October 3, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gilbert Marchal, M.D.
President
Southend Medical Clinic, P.S.C.
5129 Dixie Highway
Louisville, KY 40216

Facility I.D.#: 210419

Dear Dr. Marchal:

A representative from the Commonwealth of Kentucky acting on behalf of the Food and Drug Administration (FDA) inspected your facility on September 26, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

Quality Assurance – Equipment - 21 CFR 900.12(e)(1)(i)-(iii)

Your records showed that your facility processed mammograms when the processor quality control records were missing 17 of 27 days or 63% of total days of operation in August 2001.

The inspection revealed that during the weeks of August 13-17 and 20-24, 2001 your facility did not perform the daily quality control tests on the processor used to process mammograms. The inspection revealed that during these weeks, your facility operated without any available sensitometer and densitometer. Your staff indicated these meters were shipped to a vendor for calibration. Your facility could not perform properly the alternative procedure by conducting daily phantom quality control tests. The alternative procedure of conducting daily phantom quality control test also requires the use of a densitometer.

Because this condition may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, this represents violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of

your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

In addition, your response should address the Level 2 noncompliance items that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliance items are:

1. Quality Assurance – Equipment - 21 CFR 900.12(e)(2)

Your records revealed that your facility phantom quality control records for the mammography unit were missing for two (2) weeks. The MQSA regulation requires the mammography unit be evaluated by performing at least weekly the image quality evaluation test.

As indicated in a previous paragraph, the inspection found that your facility failed to properly perform this quality control test during the weeks of August 13-17 and August 20-24, 2001.

2. Quality Assurance – Equipment - 21 CFR 900.12(e)(9)(i)-(v)

The time period between the previous and current medical physicist surveys for the mammography unit at your facility exceeded 14 months.

The inspection found the previous medical physicist survey was conducted on May 9, 2000 and the subsequent survey was conducted on July 16, 2001.

You must act on these matters immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter; and
- Each step your facility is taking **to prevent the recurrence of similar violations.**

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

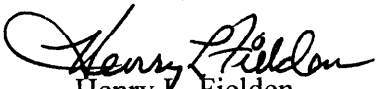
Also, please **send a copy** to the State radiation control office:

Mr. Steve Mays
Commonwealth of Kentucky
Radiation Health & Toxic Agents Branch
Mailstop HS 2E-D
275 East Main St.
Frankfort, KY 40621

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,



Henry L. Fielden
District Director
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c.
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